

Appl. No. 10/539,797
Amendment dated: July 14, 2008
Reply to OA of: April 14, 2008

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claims 1-13(canceled).

14(original). An assay method for the determination of calprotectin in a calprotectin-containing body fluid, said method comprising the steps of:

(a) obtaining a calprotectin-containing liquid sample of, or derived from, said fluid;

(b) contacting said sample of said body fluid with a nanoparticle-bound anti-calprotectin antibody or antibody fragment, to bind said calprotectin; and

(c) assessing the calprotectin content by turbidimetry,
wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 65-140 nm.

15(original). A method as claimed in claim 14 wherein the diameter of the antibody or antibody fragment coated nanoparticles is in the range 75-120 nm.

16(previously presented). A method as claimed in claim 14 wherein said nanoparticles are substantially all of the same size (e.g. monodisperse).

17(previously presented). A method as claimed in claim 14 wherein an opacity enhancer is added in between steps (b) and (c).

18(previously presented). A method as claimed in claim 14 wherein said body fluid is selected from blood, serum, plasma, urine, cerebrospinal fluid, oral fluid, synovial fluid or empyema fluid.

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19(previously presented). A method as claimed in claim 14 performed as an automated assay.

20(currently amended). A kit for use ~~[[as]]~~ in a diagnostic assay method ~~according to claim 14~~ comprising:

one or more anti-calprotectin ~~antibodies~~ antibody or antibody fragments fragment ~~immobilised on~~ coated nanoparticles having a diameter in the range 65-140 nm, wherein said assay method comprises:

- (a) obtaining a calprotectin-containing liquid sample of, or derived from, said fluid;
- (b) contacting said sample of said body fluid with said nanoparticle-bound anti-calprotectin antibody or antibody fragment, to bind said calprotectin; and
- © assessing the calprotectin content by turbidimetry.

21(original). A kit as claimed in claim 20 further comprising a calprotectin solution of known concentration or a set of such solutions having a range of calprotectin concentrations.

22(previously presented). A kit as claimed in claim 20 further comprising a light transmitting vessel.

23(previously presented). A kit as claimed in claim 20 further comprising an opacification enhancer.

24(previously presented). A kit as claimed in claim 20 further comprising a detector.

25(canceled).

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26(previously presented). A method of diagnosis of a disease comprising the method as claimed in claim 14 followed by comparison of said calprotectin content with a predetermined threshold value wherein said disease is selected from rheumatic diseases, Sjögrens syndrome, intraocular inflammatory conditions, cystic fibrosis, acute and chronic lung disease, lung carcinoma, pulmonary cancers, colorectal cancer, inflammatory bowel disease, gastric cancer, colorectal adenoma or cancer, Chrohn's disease, ulcerative colitis, gastrointestinal mucosal inflammation, urinary stones, alcoholic liver disease, oral inflammatory mucosal disease, CNS inflammatory disease, HIV infection, secondary CNS infections in HIV infected patients, urinary tract infections, cystitis, pyelonephritis, endogenous posterior uveitis, haematological conditions, febrile conditions (infectious and non-infectious), CVD, acute myocardial infarction and apheresis.

27(original). A method of diagnosis as claimed in claim 26 wherein said disease is CVD.